



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

JAN 8 2009

Re: Avastin  
Docket Nos. FDA-2004-E-0519  
FDA-2007-E-0102

The Honorable Jon Dudas  
Under Secretary of Commerce for Intellectual Property  
Director of the United States Patent and Trademark Office  
Mail Stop Hatch-Waxman PTE  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the patent term extension applications for U.S. Patent Nos. 6,054,297 and 6,639,055 and filed by Genentech, Inc. under 35 U.S.C. § 156. The patents claim Avastin (bevacizumab), biologics license application (BLA) 125085/0.

In the September 20, 2006, issue of the Federal Register (71 Fed. Reg. 54997), and the May 14, 2008, issue (73 Fed. Reg. 27836), the Food and Drug Administration published its determinations of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The May 14, 2008, notice provided that on or before November 10, 2008, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day periods for filing a due diligence petition pursuant to these notices have expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

cc: Jeffrey P. Kushan  
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